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TITLE: Reintegration: The Role of Spouse Telephone BATTLEMIND

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INVESTIGATOR:

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The study enrolled 6	60 OEF/OIF spouses	from the general popu	lation of spouses. In a	addition, per the	e request of the Wounded Warrior
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Introduction

The goal of this study is to help spouses serve as a support system and ease the transition for military service members returning from Operation Enduring Freedom/Operation Iraqi Freedom (OEF/OIF). The program provides telephone support group sessions to spouses designed to educate, build coping skills, improve access to services for veteran and family, and serve as a source of shared support. The study is based on the BATTLEMIND Training System developed by the Walter Reed Army Institute of Research to help soldiers reintegrate and adapt their combat skills back into civilian life. Topics for the Spouse Telephone Support Groups are based on the letters of the word BATTLEMIND.

The study was designed for 60 OEF/OIF spouses from the general population of spouses. Per the request of the Wounded Warrior Program (WWP), 26 WWP spouses have been enrolled. Over the period of one year, each group of 6 participants (or approximately 10 participants for the WWP spouses) and a trained Group Leader will have 12 hour-long structured telephone sessions, focusing on education, coping skills, and support. The content includes ways the returning service member, spouse and family may have changed during deployment; an emphasis on compromise and negotiation in personal relationships; strategies to reduce or eliminate reunion and reintegration difficulties; strategies to support the returning soldier; and cues to alert spouses when to seek mental health services for their soldier, children, or themselves.

Body

During this year, the project, budget and SOW were amended and approved to include the WWP spouses. Approval was received from the Memphis VAMC IRB and HRPO to recruit additional spouses. The complete amended SOW is shown as Appendix 1.

Task 1: Develop Manual of Operations (MOP), September 2008 – March 2009. All MOP tasks were completed in the previous year. Amendments to the MOP were made this year for WWP spouses. All activities for Task 1 are complete.

Products for Task 1 include:

• Completed Manual of Operations

Task 2: IRB approval, August 2008 – September 2008, February 2010 – March 2010. IRB approval to recruit the WWP spouses and an amended consent form was obtained on March 30, 2010. HRPO approval was obtained on July 13, 2010. All activities for Task 2 are complete.

Products for Task 2 include:

• Approved consents and amendments

Task 3: Hire and train personnel, September 2008 – January 2009. A new Group Leader was hired this year and certified this year. An Anthropology graduate student has begun working with qualitative data from one-on-one calls. We do not anticipate any additional hiring, although a University of Memphis Psychology graduate student and Public Health graduate student may be working with the project in the near future.

Products for Task 3 include:

• Trained and certified staff

Task 4: Recruitment, April 2009 – January 2010, April 2010 – June 2010. All activities are completed for this task. Recruitment is closed. Clinical Trials website has been updated to reflect this information.

Products for Task 4 include:

- 60 regular spouse participants recruited
- 26 Wounded Warrior Program spouse participants recruited

Task 5: Intervention (Telephone Groups), April 2009 – July 2011. To date, two support groups are completed and 9 for regular participants and 3 for WWP participants are ongoing.

Ongoing activities for Task 5 include:

• Provide telephone groups for intervention participants

Products for Task 5 include:

- Groups provided for 60 participants plus up to 30 Wounded Warrior participants
 - o Twelve support groups ongoing
 - o Two support groups completed

Task 6: Data Collection/Data Entry/Cleaning, April 2009 – July 2011.

Completed activities for Task 6 include:

• Collect full data at baseline

Ongoing activities for Task 6 include:

- Collect full data at six and twelve months
- Enter and clean data

Products for Task 6 include:

- 86 completed baseline batteries for participants
- 46 completed 6-month batteries for participants
- 6 completed 12-month batteries for participants
- All baseline data are entered and cleaned
- All other 6 and 12-month data are entered

Key Research Accomplishments. None to date.

Reportable Outcomes. None to date.

Conclusion. None to date.

References. N/A

Appendices. Amended and approved SOW.

Supporting Data. N/A

STATEMENT OF WORK (SOW) Amendment 7/7/10

Task 1: Develop Manual of Operations (MOP)

September 2008 – March 2009

- Finalize support group format
 - Develop outline and scripts for each educational/coping skills BATTLEMIND section/topic
- Finalize support group materials
 - Develop/modify/obtain support group educational/coping skills material
 - Compile internet resources (VA, DoD, National Center for PTSD)
 - Prepare Participant Notebooks and Welcome Packs
- Finalize screening materials
 - Finalize inclusion/exclusion criteria
 - Finalize forms and scripts
- Finalize data collection protocol/battery
 - Develop/modify forms and write scripts for each section of the battery
 - Write supporting documentation (e.g., Q by Qs for battery)
 - Identify participant alerts (e.g., depression) and appropriate actions to take
- Develop and print brochures and posters

Task 1: Products/Outcomes

- Manual of Operations
 - Support group format, topics and scripts
 - Material for each topic
 - Internet resources document
 - Participant Notebooks and Welcome Packs
 - Screening forms and scripts
 - Data collection forms and scripts and supporting documentation
- Brochures and posters

Task 2: IRB approval August 2008 – September 2008, February 2010 – March 2010

- Develop informed consent documents and obtain IRB approval
- Amend informed consent and protocol to include 30 Wounded Warrior participants

Task 2: Outcomes/Products

Approved consent

Task 3: Hire and train personnel

September 2008 – January 2009

Task 3: Outcomes/Products

• Trained and certified staff

Task 4: Recruitment

April 2009 – January 2010, April 2010 – June 2010

- Work with recruitment sources
- Send brochures to spouses or significant others of returning personnel who are at least 1 month post deployment
- Telephone and screen potential participants

Task 4: Products/Outcomes

• 60 participants recruited

Additional 30 Wounded Warrior Program participants to be recruited

Task 5: Intervention (Telephone Groups)

April 2009 – July 2011

- Schedule groups
- Provide telephone groups for intervention participants

Task 5: Products/Outcomes

• Groups provided for 60 participants plus up to 30 Wounded Warrior participants

Task 6: Data Collection/Data Entry/Cleaning

April 2009 – July 2011

- Collect full data at baseline, six and twelve months
- Enter and clean data

Task 6 Products/Outcomes

• Completed data collection batteries for participants

Task 7: Data Analysis

June 2010 – September 2011

Analyze data

Task 7: Products/Outcomes

• Completed data analysis (characteristics of participants, participant satisfaction, adherence to therapeutic recommendations; feasibility and cost, clinical and social impacts)

Task 8: Preparation and Dissemination of Results

March 2011 – November 2011

- Prepare papers and presentations
- Develop protocol for dissemination to other VAMCs, Vet Centers, and DoD facilities

Task 8: Products/Outcomes

- Papers and Presentations
- Manuals and materials and plan for dissemination to other VAMCs, Vet Centers, and DoD facilities

Study Site Information: No animal use/anatomical samples

VA Medical Center Memphis - All activities including human subject use (n=86) at this site only (11H) 1030 Jefferson Avenue

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